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No. 01-

IN THE
Supreme Court of the United States

BILLYE JEAN MARTIN AND LIRBA SALAZAR,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court held that the state-law damages claims at issue there were not preempted by the Medical Device Amendments ("MDA") to the Food Drug and Cosmetic Act, 21 U.S.C. 360k(a). The Court did not, however, explicitly decide whether its no-preemption ruling applies where the medical device alleged to have caused the plaintiff's injury has been granted pre-market approval by the Food and Drug Administration ("FDA"). Since *Medtronic*, the lower federal courts and state courts of last resort have become deeply divided over that question. *Compare, e.g., Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (no preemption); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999) (same), *with, e.g., Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (preemption), *cert. denied*, 523 U.S. 1020 (1998); *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I.) (same), *cert. denied*, 522 U.S. 952 (1997). In addition, the United States has taken the position that pre-market approval does not trigger preemption. *See infra* at 20.

The question presented is:

> Did the court below err in holding that petitioners' state-law damages claims are expressly preempted by the MDA solely because the FDA had granted pre-market approval for the medical device alleged to have caused petitioners' injuries?

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Billye Jeanne Martin and Lirba Salazar respectfully request that the Court issue a writ of certiorari to review the Fifth Circuit's ruling that their state-law damages claims, seeking recovery for injuries caused by a medical device, are preempted by the Medical Device Amendments to the federal Food, Drug, and Cosmetic Act.

OPINIONS BELOW

The opinion of the Fifth Circuit is reported at 254 F.3d 573, and is reproduced in the appendix to this petition at 1a. The United States District Court for the Southern District of Texas issued two relevant decisions in each of petitioners' cases, none of which are reported. The decisions in Ms. Martin's case are reproduced at 23a and 33a. The decisions in Ms. Salazar's case are reproduced at 36a and 46a.

JURISDICTION

The judgment of the Fifth Circuit was entered on June 18, 2001 (1a). This Court has jurisdiction under 28 U.S.C. 1254(1).

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. 360k provides in part:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for

human use any requirement—

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. 808.1(d) provides in part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in

which the requirements are not limited to devices....

STATEMENT OF THE CASE

Introduction

Petitioners Billye Jeanne Martin and Lirba Salazar were implanted with a pacemaker lead manufactured by respondent Medtronic, Inc. The lead is a wire that delivers an electrical impulse from a pacemaker's "pulse generator" to the patient's heart. Because of defects that ultimately led to withdrawal of the product from the market, their leads malfunctioned, causing them damages, including medical expenses, physical injuries, pain and suffering, and other losses. Both Ms. Martin and Ms. Salazar filed suit against respondent, and because their cases presented the identical legal question they were consolidated on appeal by the U.S. Court of Appeals for Fifth Circuit. This petition presents the question whether petitioners may seek recovery for their injuries under Texas law, or whether, as respondent maintains and the Fifth Circuit below held, the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act — enacted in 1976 to protect consumers from potentially dangerous medical devices — bar them from recovering their damages.

The Court should grant review for two related reasons. First, since the Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the federal and state appellate courts have become deeply divided on the precise question presented here: whether state-law damages claims concerning medical devices that have been approved by the Food and Drug Administration ("FDA") under the MDA's pre-market approval ("PMA") process are preempted. In fact, three circuit courts have now reviewed the same FDA approval with respect to the same medical device, made by the same company, and reached

exactly opposite results. *Compare Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (applying *Lohr* and finding no preemption of state-law damages claims), *with* 1a (Fifth Circuit decision below, applying *Lohr* and finding preemption of all state-law damages claims) and *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) (same), *pet. for cert. pending*, No. 00-1766 (filed May 24, 2001). *See also, e.g., Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999) (finding no preemption on same issue).

Second, the Court should grant review because a significant number of appellate courts have erroneously reaffirmed broad pre-*Lohr* interpretations of the MDA's preemption provision, 21 U.S.C. 360k(a). Like the decision below, these courts have mistakenly held that the FDA's approval of a PMA application constitutes a specific preemption-triggering federal "requirement" under section 360k(a) and have failed to follow *Lohr*'s holding that claims based on state-law duties of general applicability are not preempted. *See Lohr*, 470 U.S. at 501-02.

Part A below describes the structure of the MDA, and Part B discusses this Court's decision in *Medtronic v. Lohr, Inc.*, which interpreted the MDA's preemption provision and has spawned conflicting views in the state and federal appellate courts on the meaning of that provision. Part C explains the factual background and district court proceedings in this case. Finally, Part D describes the holding of the Fifth Circuit below.

A. The Medical Device Amendments.

The principal purpose of the MDA was to increase consumer protection by preventing the distribution of dangerous medical devices and by providing a process by which devices could reach the market. H.R. Rep. 853, 94th

Cong., 2d Sess. 1-12 (1976); *see* P.L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. 360c *et seq.*). Every medical device falls into one of three classes. In general, as health risks from a device increase, so does regulatory scrutiny under the MDA. H.R. Rep. 853, *supra* at 34; 21 U.S.C. 360c(a). Class I devices, such as band aids, are the least risky and are subject only to "general controls" applicable to all devices, such as general labeling requirements and good manufacturing practices rules promulgated by the FDA, the agency charged by Congress with implementing the MDA. *See id.* § 360c(a)(1)(A).

Class II devices are more likely than class I devices to cause harm if they are defective or misused. *Id.* § 360c(a)(1)(B). Thus, the FDA may subject them to "special controls," such as the agency's specific warning labels for tampons. *See* 21 C.F.R. 801.430(c), (d) & (e).

Finally, class III devices — such as the pacemaker leads at issue here and in *Lohr* — are those that, in general, cannot be marketed until the FDA has found that the device presents a reasonable assurance of safety and effectiveness. 21 U.S.C. 360c(a)(1)(C). This process is known as pre-market approval, or PMA. *Id.* § 360e(b)(1)(A).[1]

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[1]Certain class III devices, such as the one at issue in *Lohr*, can be marketed without going through the full PMA process. If the FDA finds that a Class III device is "substantially equivalent" to a device marketed prior to the MDA's effective date, or to a device that itself was found to be "substantially equivalent" to a pre-MDA device, that device need not obtain PMA until the FDA issues a regulation requiring PMA for that type of device. 21 U.S.C. 360e(b)(1)(B), 360c(f)(1)(A). The FDA's process for

(continued...)

Three components of the regulatory structure are relevant to this petition. First, when it approves a manufacturer's PMA application, the FDA does not warrant that the device is free of defect in design, manufacture, or labeling. And, of critical importance here, the FDA does not, as part of the PMA process, require or specify the device's design, manufacturing process, or labeling, nor does it conduct testing or studies regarding the device. Rather, a device's design, manufacture, and labeling originate with the applicant (the device manufacturer), on whose data the FDA depends in acting on the PMA application. 21 C.F.R. 814.20, 814.44. As in this case, the FDA issues a form approval letter reminding the manufacturer of its obligations under federal regulations. There is nothing device-specific in the form approval letter.

Second, in a few instances, the FDA has issued device-specific requirements for particular types of devices. For instance, in addition to the tampon warning label mentioned above, the FDA has required that hearing aids bear certain labels and that tampon absorbency be tested in a specific manner. *See* 21 C.F.R. 801.420, 801.430(f). The FDA has never promulgated any such device-specific requirements for pacemakers or their component parts, such as the pacemaker lead that caused petitioners' injuries.

Third, the MDA contains a preemption provision, 21 U.S.C. 360k(a), which preempts certain state-law "requirements" "with respect to a device" if they are "different

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[1](...continued)
approving such devices is sometimes referred to as the "510(k)" process after the section of the Food, Drug, and Cosmetic Act under which the device application is submitted. *See Lohr*, 518 U.S. at 478.

from, or in addition to" MDA "requirements." Under 21 U.S.C. 360k(b), the FDA has the authority to exempt from preemption certain state requirements that would otherwise be preempted. Thus, the FDA has issued regulations concerning the scope of MDA preemption, *see generally* 21 C.F.R. Part 808, which reflect section 360k(a)'s narrow reach. *See Lohr*, 470 U.S. at 498 n.18 ("FDA's narrow understanding of the scope of § 360k(a) is obvious from the full text of the regulation"). For instance, the regulations require that for an FDA requirement to have preemptive effect, it must establish a device-specific "counterpart" to a "divergent" state-law requirement. 21 C.F.R. 808.1(d). Likewise, to be preempted, state-law requirements also must be "specific." Thus, preemption does not extend to state requirements of "general applicability where the purpose of the requirement relates ... to other products in addition to devices." *Id.* § 808.1(d)(1).

B. The Decision in *Medtronic v. Lohr*

In *Lohr*, plaintiff Lora Lohr filed suit under Florida law for damages resulting from an allegedly defective class III pacemaker lead that the FDA had cleared for marketing under its section 510k "substantial equivalence" process. This Court held that none of Lohr's claims — based on defective design, defective manufacture, and failure to warn — was preempted by the MDA.

1. *The Majority Opinion.* Although there was a concurrence and a partial dissent in *Medtronic*, the majority opinion contains three holdings in which all members of the Court concurred: (1) The MDA does not broadly preempt all state-law damages claims against device manufacturers, *see Lohr*, 470 U.S. at 480; *id.* at 505 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); (2) Lohr's design-

defect claim was not preempted because the FDA had not issued any design specifications for the device in question, *id.* at 492-94; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); and (3) a tort claim premised on state-law duties "equal to, or substantially identical to, requirements" imposed under the MDA or FDA regulations are not preempted. *Id.* at 494-97; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

By a 5-4 margin, in Part V of the *Lohr* majority opinion, the Court also held that Lohr's manufacturing-defect and failure-to-warn claims were not preempted, even if they did more than seek to enforce the federal requirements. The Court looked to the language of the MDA's preemption provision and the FDA's preemption regulations and noted the "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Id.* at 500. The generality of the FDA's manufacturing and labeling regulations applicable to the pacemaker lead, the Court held, precluded a finding of preemption. Those federal requirements, the Court said, reflect "important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 501.

The Court further noted that Lohr's damages claims were premised on general state-law duties that did not focus specifically on medical devices. Thus, the Court found, the general state-law duties to use due care in manufacturing and to warn users of potential risks are not the types of requirements that Congress or the FDA feared would impede the FDA's ability to enforce specific federal laws and regulations. Because they were based on general principles of state law, the

majority held, the claims were outside of the prohibited category of state-law requirements "with respect to" specific devices within the meaning of section 360k(a). *Id.* at 501-02.[2]

2. *The Concurrence.* Justice Breyer filed a concurring opinion stating that, in his view, section 360k(a)'s reference to state-law "requirements" encompasses state-law damages claims. He therefore did not join the plurality opinion (*see supra* note 2), because he was not convinced that MDA preemption of damages claims would be "rare." *Id.* at 508. He joined fully, however, in Part V of the majority opinion, discussed immediately above, which demanded specificity on both the state and federal sides of section 360k(a)'s preemption analysis. He stated that the applicable FDA requirements that were related to Lohr's claims were not "specific" in any relevant sense and deferred to the FDA's preemption regulation, 21 C.F.R. 808.1(d), which amplifies the meaning of section 360k(a)'s specificity requirement. 470 U.S. at 505-06 (citing, *e.g., Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984)). He noted that the language of section 360k(a) reflected basic principles of conflict preemption, but found no conflict between any federal requirement and any of Lohr's claims. *Id.* at 506.

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[2]Speaking for a four-Justice plurality, the lead opinion also relied on the MDA's language and history to conclude that section 360k(a) was not intended to preempt most, and perhaps any, damages claims. *Id.* at 488-91 (distinguishing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)). The plurality found it unnecessary to decide whether section 360k(a) reached any damages claims, however, because, under the majority's more focused analysis, none of Lohr's claims was preempted. *Id.* at 502-03.

3. *The Partial Dissent.* Justice O'Connor dissented in part and concurred in part, joined by the Chief Justice and Justices Scalia and Thomas. In her view, state-law damages claims can constitute "requirements" under section 360k(a). *Id.* at 509-11. Although concurring with the majority that Lohr's design-defect claim was not preempted, she would have held that the manufacturing-defect and failure-to-warn claims were preempted to the extent that they sought to impose requirements different from those imposed by the FDA's manufacturing and labeling rules. *Id.* at 513-14. She agreed with the majority that Lohr's manufacturing-defect and failure-to-warn claims were not preempted to the extent that they alleged violations of federal requirements. *Id.* at 513.

C. Background Facts and District Court Proceedings.

As noted earlier, although this petition involves two separate lawsuits filed by two different individuals, both cases concern the same legal issue and involve the same medical device. The product that caused petitioners' injuries is Medtronic's 4004 pacemaker lead. 2a-3a. The FDA approved Medtronic's application in March 1990, as a supplement to a pre-market approval ("PMA") that had been granted to an earlier version of the device. *See* 25a.

After the product's approval, it was discovered that the 4004 ran a significant risk of failure caused by degradation of its polyurethane insulation. As a result, in October 1993, respondent issued a "Health Safety Alert" to the medical community and withdrew the remaining 4004 leads from the market. *See Kemp,* 231 F.3d at 219. Unfortunately, the 4004's withdrawal came too late for Ms. Martin and Ms. Salazar, who had already been implanted with the defective device. *See* Original Petition in *Martin*, ¶ IV; Complaint in *Salazar,* ¶ IV.

Ms. Salazar brought suit in August 1996, based on diversity of citizenship under 28 U.S.C. 1332, in the United States District Court for the Southern District of Texas. In the same month, Ms. Martin brought suit in state court in Nueces County, Texas, and respondent removed the case to the same federal court on diversity grounds under 28 U.S.C. 1441(a). Thereafter, although the two cases were not consolidated, the district court heard them together, and its orders regarding preemption in the two cases are nearly identical. The complaints in both cases allege claims based on negligence, gross negligence, strict liability, breach of warranty, and violation of the Texas Deceptive Trade Practices Act, Tex. Bus. & Com. Code 17.41 *et seq.* Original Petition in *Martin*, ¶¶ VIII-XII; Complaint in *Salazar*, ¶ V; *see* 3a. In particular, petitioners' DPTA claims alleged breaches of express and implied warranties, failure to disclose known defects, misrepresentation, and unconscionability. *See* Tex. Bus. & Com. Code 17.46(b)(2), (5), and (7), 17.50 (a)(2) and (3). Petitioners' claims focused on defects in the design and manufacture of the pacemaker lead and the failure of respondent to warn about the product's hazards. 3a.

The district court held that all of petitioners' claims are preempted by the MDA, and granted summary judgment to respondent. The district court noted that, prior to this Court's decision in *Lohr*, the Fifth Circuit had held that design-defect and failure-to-warn claims with respect to a device that had undergone FDA pre-market approval are preempted by the MDA. *See* 28a, 41a (citing *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993)). The court stated that *Lohr*'s no-preemption holding was "distinguishable" from *Stamps* because the device in *Lohr* had not gone through the PMA process. The court thus ruled that all of petitioners' claims challenging the design and manufacture of the 4004 lead, as well as all claims based on failure to warn, are preempted (31a, 43a-44a), but held

that any claim that respondent did not use the PMA processes actually approved by the FDA would not be preempted and granted petitioners time to develop such a claim. Petitioners did not pursue that claim and the court thereafter granted respondent final summary judgment on preemption grounds. 33a-35a, 46a-48a.

D. The Fifth Circuit's Decision.

The Fifth Circuit affirmed the grant of summary judgment to respondent on all of petitioners' state-law damages claims. The court began by noting that under its pre-*Lohr* decision in *Stamps v. Collagen Corp.*, 984 F.2d 1416, petitioners' claims would be preempted. 2a. Calling its earlier ruling "central to our resolution of this appeal," 5a, the court stated that "*Stamps* should apply to this case unless 'an intervening Supreme Court case explicitly or implicitly overrule[es] that prior precedent.' ... Thus, the first, and ultimately only, question we face is the degree to which *Stamps* retains precedential value after the Supreme Court's decision in *Lohr*." 6a (quoted case citation omitted).

The court stressed that "the Supreme Court decision must be more than merely illuminating with respect to the case before us, because a panel of this court can only overrule a prior panel decision if 'such overruling is unequivocally directly by controlling Supreme Court precedent.'" 6a (quoted case citation omitted). "[O]ur question," the court later noted, "is not whether the panel in *Stamps* correctly decided the case, but whether the Supreme Court overruled *Stamps*." 12a n.5.

The court of appeals "immediately conclude[d]" that *Lohr* neither explicitly overrules *Stamps* nor "implicitly requires us to disregard *Stamps* as controlling precedent." 12a. It then considered whether the state-law duties upon which petitioners'

damages actions rely were the kinds of requirements targeted for preemption under section 360k(a). The court recognized the *Lohr* majority's view that claims based on state product liability duties generally "escape preemption ... because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with-respect to' specific devices such as pacemakers." 14a (quoting *Lohr*, 518 U.S. at 501, in turn quoting 21 U.S.C. 360k(a)). It acknowledged that it was "plainly bound" to follow a majority opinion of this Court (15a), but it did not feel so constrained here, because it read Justice Breyer's joinder in it as limited to the 510k substantial equivalence process at issue in *Lohr*, not the PMA process at issue in *Stamps*. 16a. The court of appeals thus adhered to *Stamps*'s holding that product-liability claims alleging defects in a medical device "create specific requirements under state law." 16a. The Fifth Circuit did not consider the FDA's preemption regulation, 21 C.F.R. 808.1(d), which, like the *Lohr* majority opinion, states that state-law requirements of "general applicability" are not preempted under section 360k(a).

The court then addressed the question whether the PMA process imposes specific preemptive requirements. 21a. *Stamps* controlled, the court held, because it concerned the PMA process while *Lohr* dealt with what it termed the less "specific" 510k process. Having thus decided that "*Lohr* does nothing to upset *Stamps*'s binding authority" (22a), the Fifth Circuit concluded that all of petitioners' tort claims are preempted.

REASONS FOR GRANTING THE WRIT

A. This Court's Guidance Is Needed To Resolve A Deep Post-*Lohr* Division Among The Federal And State Appellate Courts.

The decision below illustrates a deep post-*Lohr* split in authority in two important and related respects. First, the decision below widens the division among the federal circuit courts and state courts of last resort on the issue that was determinative in the court below: whether the FDA's grant of PMA for a medical device triggers preemption of state-law damages claims alleging that a manufacturer did not properly design and manufacture the device and failed to warn of the device's inadequacies. Some courts, including the Eleventh Circuit, hold that PMA does not trigger preemption under section 360k(a) and that, therefore, state-law damages actions alleging injuries caused by PMA devices are not preempted. Other courts agree with the Fifth Circuit that PMA does, in fact, trigger preemption. *Compare, e.g., Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (no preemption); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999) (same), *with, e.g., Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) (preemption), *pet. for cert. pending*, No. 00-1766 (filed May 24, 2001); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (same), *cert. denied*, 523 U.S. 1020 (1998); *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I.) (same), *cert. denied*, 522 U.S. 952 (1997). As explained below in Part B, petitioners believe that the no-preemption rulings are better reasoned because they are truer to the text and purpose of section 360k(a) as construed by this Court in *Lohr*. For present purposes, however, the key point is that there is substantial conflict on an important and recurring issue of federal law that is significant to medical device patients, the industry that makes

those devices, and the federal agency that regulates them.

Second, the courts of appeals and the state appellate courts are divided in their application of the analytic framework set forth in *Lohr* for resolving express preemption questions under 21 U.S.C. 360k(a). As noted above, *Lohr* requires that, before preemption may occur, both the allegedly preemptive federal requirement and the allegedly preempted state-law requirement must be "specific" within the meaning of section 360k(a) and regulations promulgated thereunder. *See* 21 C.F.R. 808.1(d).

1. Looking first to the federal-law side of section 360k(a)'s preemption inquiry, *Lohr* held that, to have preemptive effect under 21 U.S.C. 360k(a), the federal requirement must be specific. Thus, a specific labeling requirement for a particular type of device might have preemptive effect (*see, e.g.*, 21 C.F.R. 801.430), in contrast to the comprehensive, but general, good manufacturing and labeling regulations that the Court held did not have preemptive effect. 470 U.S. at 497-99. In his concurrence, Justice Breyer suggested that an example of this type of specific federal requirement would be an FDA rule that a particular hearing-aid component be built with two-inch wires. *See id.* at 504.

Although the FDA's criteria for PMA applications are general and do not require devices to be designed, manufactured, or labeled in any particular manner, the Fifth Circuit nonetheless held, based on its prior ruling in *Stamps*, that the PMA process was a "specific" requirement as applied to the FDA's review of the 4004 lead. 21a. *Accord, e.g.*, *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376 (Tex.), *cert. denied*, 524 U.S. 954 (1998); *Fry*, 695 A.2d at 516; *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, 520 U.S. 1168 (1997); *Steele v. Collagen Corp.*, 63 Cal. Rptr. 879, 887-

88 (Cal. App. 1997). But as the Fifth Circuit recognized in citing the Eleventh Circuit's ruling in *Goodlin* (12a n.5), other appellate and trial courts have come to the opposite conclusion, holding that the PMA process itself is not a specific requirement under *Medtronic*. *Goodlin*, 167 F.3d at 1373-77; *Weiland*, 721 N.E.2d at 1152-53; *Sowell v. Bausch & Lomb*, 656 N.Y.S.2d 16, 20-21 (N.Y. App. Div. 1997); *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W. 2d 679, 684 (Mich. App. 1996); *Haidak v. Collagen Corp.*, 67 F. Supp.2d 21, 23-24 (D. Mass. 1999) (*Lohr* effectively overrules pre-*Lohr* First Circuit decision ascribing preemptive effect to PMA); *Lakie v. SmithKline Beecham*, 965 F. Supp. 49 (D.D.C. 1997); *Quillen v. American Hosp. Supply Corp.*, 1997 U.S. Dist. Lexis 6974, *14-*15 (N.D. Okla. Mar. 31, 1997).[3]

2. The split in authority is also profound on the state-law side of *Lohr*'s preemption analysis. The Fifth Circuit below

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[3]Similarly, two state Supreme Courts have held that state-law damages claims involving class III devices marketed under the MDA's investigational device approval process (*see* 21 U.S.C. 360j(g)) — which is often a precursor to the PMA process — are not preempted because that process does not establish specific requirements under *Medtronic*. *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc), *cert. dismissed*, 520 U.S. 1260 (1997); *Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997). *But see Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095 (6th Cir. 1997), *cert. denied*, 522 U.S. 1075 (1998) (investigational device process does establish preemptive federal requirements). *See also Worthy*, 967 S.W.2d at 374 (noting conflict in appellate authority over preemptive effect of MDA's investigational device provisions and claiming that PMA and investigational processes are comparable).

acknowledged *Lohr*'s holding that damages claims are not preempted if they are premised on general state-law duties that do not focus specifically on medical devices, and understood that it would, if applied to these cases, require a ruling in favor of petitioners. 14a-16a; *see also Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997). The court of appeals did not follow that majority holding, however, on the ground that it is incompatible with Justice Breyer's *Lohr* concurrence. 14a; *see also Papike*, 107 F.3d. at 742; *Mitchell*, 126 F.3d at 912; *Papike*, 107 F.3d at 742; *Steele v. Collagen Corp.*, 63 Cal. Rptr. 879, 887 (Ct. App. 1997); *Fry*, 695 A.2d at 517. As discussed below (at 21-22), these appellate courts erred in applying *Lohr*'s majority holding. On the question whether this Court should grant review, however, the significance of these rulings is that they are at odds with the decisions of other appellate courts that have held that this Court meant what it said in *Lohr*: State laws of general applicability are not among those laws targeted for preemption by section 360k(a).

For instance, in *Oja v. Howmedica*, 111 F.3d 782 (10th Cir. 1997), the plaintiff claimed that the defendant had failed to warn her about problems with a hip replacement device. The Tenth Circuit agreed with the defendant that there was at least one specific FDA-mandated warning that constituted a federal device "requirement" within the meaning of section 360k(a), but held that the plaintiff's failure-to-warn claim was not preempted because it was not based on a law relating specifically to medical devices:

> Like the failure to warn claim at issue in *Medtronic*, the general state common law requirements imposed by Oja's negligent failure to warn claim were not specifically developed "with respect to" medical devices. Instead, Oja's negligent failure to warn claim is predicated upon a general duty applicable to every

> manufacturer "to inform users and purchasers of potentially dangerous items of the risks involved in their use."

Id. at 789 (quoting *Lohr*, 470 U.S. at 501) (internal citations omitted).

Other appellate courts have come to the same conclusion. *See Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997) (no preemption because "Kentucky's strict liability case law and statutes [on which plaintiff relies] are laws of general applicability to all products and fall beyond the scope of the federal preemption under § 360k"); *Walker*, 552 N.W.2d at 686 (same); *Mears v. Marshall*, 944 P.2d 984, 993-95 (Ore. App. 1997) (same), *review denied*, 961 P.2d 217 (Ore. 1998); *Wutzke v. Schwagler*, 940 P.2d 1386, 1391-92 (Wash. App. 1997) (same), *review denied*, 953 P.2d 96 (Wash. 1998); *Baird v. American Med. Optics*, 693 A.2d 904, 909-10 (N.J. Super., App. Div. 1997), *modified and remanded*, 713 A.2d 1019 (N.J. 1997); *Kernats v. Smith Indus. Med. Sys.*, 669 N.E.2d 1300, 1309 (Ill. App.) ("plaintiffs' claims emanate from general common-law duties and are not the sort of state requirements that section 360k was intended to preempt"), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *cert. denied*, 522 U.S. 1044 (1998); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-72 (Cal. App. 1996)(same), *review denied*, 1997 Cal. Lexis 833 (Feb. 19, 1997); *see also Quillen*, 1997 U.S. Dist. Lexis 6974, *17-*18 (same).

This Court should grant the petition to resolve these conflicts among the federal and state appellate courts.[4]

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[4]The split in authority is particularly problematic in (continued...)

B. The Decision Below Cannot Be Reconciled With *Lohr*.

Review should also be granted because the Fifth Circuit's serious misinterpretation of *Lohr* leaves consumers injured by PMA devices without a damages remedy. In that regard, the court below erred in two fundamental ways.

First, the mere issuance of PMA is not a specific preemption-triggering requirement under section 360k(a). Although the PMA process is often more rigorous than the marketing process at issue in *Lohr*, 518 U.S. at 478-79 (explaining differences); *see also Buckman Co. v. Plaintiffs' Legal Committee*, 121 S. Ct. 1012, 1015 (2001), it is no more "specific." Both processes apply to class III devices generally, and neither specifies how a product must be designed,

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[4](...continued)
Illinois, where, if the complaint is filed in, or removed to, federal court, the plaintiff's claims are preempted, *see Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998), but if the complaint remains in state court, there is no preemption. *See Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999). The same situation exists in Kentucky. *Compare Kemp*, 231 F.3d 216 and *Martin*, 105 F.3d 1090 (broad preemption holdings applicable to cases filed in federal courts in Sixth Circuit), *with Niehoff*, 950 S.W.2d 816 (no-preemption ruling of Kentucky Supreme Court). A similar problem arises in California, where the state's own appellate courts are in conflict. *Compare Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. App. 1996) (no preemption), *review denied*, 1997 Cal. Lexis 833 (Feb. 19, 1997), *with Steele v. Collagen Corp.*, 63 Cal. Rptr. 879 (Cal. App. 1997) (preemption).

manufactured, or labeled. As the Eleventh Circuit in *Goodlin* explained, although the PMA process "differs in significant ways from the 510k process at issue" in *Lohr*, 167 F.3d at 1374, the result regarding preemption is the same: "[B]ecause the [PMA] approval itself neither reveals nor imposes any ascertainable substantive prerequisite for approval that we could compare to a purportedly conflicting state requirement, the approval itself does not fit within section 360k(a)(1)'s demand for a specific federal requirement." *Id.* at 1376; *see also id.* at 1376-77 (FDA's "conditions of [PMA] approval" are generic and thus also not preemptive). Thus, the PMA process contains no rules similar to the FDA's device-specific labeling rules (*see, e.g.*, 21 C.F.R. 801.420), or to the hypothetical FDA-required two-inch hearing-aid wire discussed in Justice Breyer's *Lohr* concurrence. *Lohr*, 470 U.S. at 504. Indeed, as the Solicitor General has noted, the PMA process itself does not impose specific federal "requirements" because the device's specifications originate with the manufacturer, not with the FDA. Brief for the United States as Amicus Curiae in *Smith Indus. Med. Sys., Inc. v. Kernats* ("United States Brief in *Kernats*"), No. 96-1405, at 16 (U.S. filed Dec. 10, 1997);[5] *cf.*

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[5]In *Smith Industries Medical Systems, Inc. v. Kernats*, No. 96-1405, in responding to this Court's request for advice on the same issue presented by this petition, the Solicitor General took the position that FDA pre-market approval does not preempt state-law damages claims. United States Brief in *Kernats*, at 14-18. The Solicitor General explained that "[t]he current division among the lower courts ... would normally provide a strong justification for this Court to grant review and definitively resolve the conflict," but recommended that review be denied because the state appellate court decision in *Kernats* was not final under 28 U.S.C. 1257. *Id.* at 10-14. He also

(continued...)

American Airlines, Inc. v. Wolens, 513 U.S. 219, 228-29 (1995).

Second, the decision below misapprehends *Lohr* in holding that petitioners' claims — and, therefore, all traditional damages claims involving a PMA device — are preempted, even though they are, without dispute, premised on state-law duties of general applicability. 3a (referring to general state-law duties on which petitioners rely); *see Lohr*, 470 U.S. at 501-02; *see also* United States Brief in *Kernats*, at 17-18 (state-law claims regarding PMA devices premised on duties of general applicability not preempted under *Lohr*). Of particular importance, the court of appeals did not mention, let alone apply, the FDA's longstanding preemption regulation, 21 C.F.R. 808.1, even though it is directly applicable here. That regulation, which was accorded substantial weight in *Lohr*, 470 U.S. at 496; *see id.* at 505-06 (Breyer, J., concurring), provides that section 360k(a) "does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to

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[5](...continued)
noted that the pendency of a proposed FDA interpretive rule regarding preemption provided another reason to deny review. *See id.* at 19-20. That proposed rule has since been withdrawn. *See* Brief for the United States as Amicus Curiae in *Buckman Co. v. Plaintiffs' Legal Committee*, No. 98-1768, at 5 n.2 (U.S. filed June 7, 2000) (petition stage). Since the Solicitor General's December 1997 filing in *Kernats*, the division among the lower courts, and thus the need for this Court's guidance, has become much more pronounced, because of the subsequent issuance of the no-preemption decisions of the Eleventh Circuit in *Goodlin* and the Illinois Supreme Court in *Weiland*, and the decision below, among others.

devices (e.g., requirements such as general electrical codes, and Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices ...." 21 C.F.R. 808.1(d)(1). The FDA's regulation encompasses petitioners' general state-law claims and explicitly refers to one of them — the Texas Deceptive Trade Practices Act, an "unfair-trade practices" law of general applicability.

As noted earlier, the Fifth Circuit disregarded the *Lohr* majority's analysis in reliance on Justice Breyer's concurrence. The simple answer, of course, is that a lower court has no warrant to disregard a majority holding of this Court. In any event, the Fifth Circuit's view is inconsistent with Justice Breyer's concurrence. Justice Breyer explained that a specific federal regulation demanding a two-inch hearing-aid wire would preempt a common-law claim premised on a specific state-law requirement for a one-inch wire. *Lohr*, 470 U.S. at 504 (Breyer, J., concurring). Petitioners' state-law damages claims, however, based on general Texas law duties to properly design and manufacture a product and to warn of its inadequacies, do not involve a specific state-law requirement of this kind, and thus their claims do not present the kind of direct conflict that concerned Justice Breyer.

In sum, review should be granted because the ruling below is at odds with this Court's decision in *Lohr*.

CONCLUSION

For the reasons stated above, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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September 2001

APPENDIX

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 99-41089

BILLYE JEANNE MARTIN,
Plaintiff-Appellant,

versus

MEDTRONIC, INC.,
Defendant-Appellee.

No. 99-41090

LIBRA SALAZAR,
Plaintiff-Appellant,

versus

MEDTRONIC, INC.,
Defendant-Appellee.

Appeals from the United States District Court
for the Southern District of Texas

June 18, 2001

Before REYNALDO G. GARZA, JOLLY, and HIGGINBOTHAM, Circuit Judges.
E. GRADY JOLLY, Circuit Judge:

In this consolidated appeal,[1] we address a question of federal preemption: whether, based on Medtronic's compliance with the Food and Drug Administration's ("FDA") rigorous premarket approval procedure ("PMA"), the plaintiffs' Texas common law products liability tort claims are preempted by 21 U.S.C. § 360k, the Medical Devices Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). We have addressed this issue before. In Stamps v. Collagen Corp., 984 F.2d 1416, 1422 (5th Cir. 1993), we held that similar state product liability claims were preempted. Since we decided Stamps, however, the Supreme Court has spoken on the issue. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 477, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). The Supreme Court did not specifically decide the case before us, yet spoke in a way that overruled Stamps in part. Lohr is a difficult opinion to apply in this case; first, because it involves a process far less specific in its requirements than the PMA process involved in both this case and Stamps, and second, because on points important to this appeal, the Lohr court was fractured. In any event, we ultimately determine that for purposes of deciding this appeal, Stamps is binding precedent that controls the outcome of the case. Accordingly, we hold that the Texas state product liability claims in this case are preempted by the MDA, and we affirm the judgment of the district court dismissing the complaint.

I

Billye Jeanne Martin and Libra Salazar each claim that they were injured by Medtronic's defective pacemaker (Model

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[1]The cases have been consolidated for the purposes of appeal only. The appellants, however, brief their appeal as if the district court considered their cases on a consolidated basis. Therefore, we treat the procedural history in the same manner.

4004). They allege that the pacemaker contained a defective "ventricular lead," the wire that carries current into the heart muscle. Their product liability claims include negligence, gross negligence, strict liability, breach of warranty, and violation of the Texas Deceptive Trade Practices Act; all claims are based on alleged deficiencies in the safety and effectiveness of the design, manufacturing process, warnings, and labeling of the lead.

The district court initially granted Medtronic's motion for summary judgment only in part, finding that the MDA preempted Salazar's and Martin's design, manufacturing process, and warning claims. The district court reasoned that in all these areas, the FDA, through its PMA procedure,[2] had approved Medtronic's product. The district court, however, denied summary judgment on the plaintiffs' claims that Medtronic had deviated from FDA requirements. Following further discovery, Medtronic renewed its summary judgment motion. The district court then granted the renewed motion, finding that appellants failed to produce evidence of alleged deviations, and entered judgment dismissing each complaint. These appeals, now consolidated, present the single issue of whether the FDA's PMA procedure preempts the state law tort claims.

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[2]Under the FDA's PMA process, the manufacturer of the medical device must submit a detailed application to the FDA, including information on product specifications, manufacturing, intended use and proposed labeling. Qualified experts review each application and prepare a report and recommendation. The FDA then has six months to accept or reject the application. See 21 U.S.C. § 360e; Stamps v. Collagen Corp., 984 F.2d 1416, 1419 (5th Cir. 1993).

II

We begin our consideration of this question of preemption by making a few preliminary observations that serve to place in context the even more precise issue before us--to what extent is our case today decided by precedents of this court and the Supreme Court. The MDA classifies medical devices into three categories based on the degree of risk they pose to the public. Class I devices pose little or no risk to public health and are subject only to general controls on manufacturing. Class II devices are potentially more harmful and may be subject to regulations and product specifications. Class III devices, the most strictly regulated, are "[d]evices that either 'presen[t] a potential unreasonable risk of illness or injury,' or which are 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.'" Lohr, 518 U.S. at 477 (quoting 21 U.S.C. § 360c(a)(1)(C)).

A pacemaker is classified as a "Class III" medical device. As such, it must undergo an indisputably thorough, rigorous, and costly premarket review (some 1,200 FDA man-hours at hundreds of thousands of dollars in cost) by the FDA. Under this PMA process, the manufacturer must give the FDA a "reasonable assurance" that the product is safe and effective. Although this term does not sound excessively demanding, the PMA process is rigorous. It requires manufacturers to submit detailed information regarding the safety and efficacy of their devices. This includes, among other things, full reports of all information that is known by the applicant, samples of both labeling and the device itself, and a full description of the methods and facilities used for manufacturing and installation of the device. See 21 U.S.C. § 360e(c)(1) (describing the components of a PMA application). The FDA then reviews the

application, spending an average of 1,200 hours on each submission before granting marketing approval. The statutory basis for this process, and its exceptions, are set forth at length in Lohr, 518 U.S. at 477, and need not be reiterated here.

It is central to our resolution of this appeal that we have held that § 360k preempts these state products liability claims when the device manufacturer complies with the FDA's PMA process. See Stamps, 984 F.2d at 1422. In this appeal, it is not disputed that Medtronic has complied with the FDA's PMA process in the creation of its pacemakers. Thus, based on the holding of Stamps, the claims here should be preempted.

But yet there is a twist. After Stamps, the Supreme Court considered the scope of MDA preemption of state law claims in the "§ 510(k) notification" process,[3] an exception to the far more demanding PMA review process. See Lohr, 518 U.S. 470. The § 510(k) process allows improvements to existing devices to be rapidly introduced into the market by foregoing the extensive review in the PMA process. Id. at 478. While the PMA process requires an inquiry into the risks and efficacy of each device through a variety of reports and submissions, as described above, the § 501(k) process only requires the manufacturer to show that the device is "substantially equivalent" to devices already on the market. Under the § 501(k) process, the manufacturer must submit proposed labeling, labels, and advertisements that describe the device, its intended use and the directions for its use; a statement indicating how the device is similar to or different from comparable products; a statement that the submitter believes that the information is accurate and complete; and any

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[3]The section number refers to the original section of the MDA containing the provision.

additional information necessary for the FDA Commissioner to make a determination as to whether the device is "substantially equivalent." See Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 121 S.Ct. 1012, 1016, 148 L.Ed.2d 854 (2001); 21 C.F.R. §§ 807.87, 807.92. The manufacturer does not have to submit information on the safety or efficacy of the device. In contrast to the 1,200 hours that it takes to complete a PMA review, a § 510(k) review takes an average of 20 hours. Lohr, 518 U.S. at 479. As the Supreme Court has noted, "[t]he § 510(k) notification process is by no means comparable to the PMA process." Id. at 478-79.

Lohr, however, is highly relevant to this appeal because it considered in some detail the preemption statute that is applicable both to the § 510(k) process and the PMA process. Notwithstanding its relevance, the Supreme Court decision must be more than merely illuminating with respect to the case before us, because a panel of this court can only overrule a prior panel decision if "such overruling is unequivocally directed by controlling Supreme Court precedent." United States v. Zuniga-Salinas, 945 F.2d 1302, 1306 (5th Cir. 1991). This means that Stamps should apply to this case unless "an intervening Supreme Court case explicitly or implicitly overrul[es] that prior precedent." United States v. Short, 181 F.3d 620, 624 (5th Cir. 1999). Thus, the first, and ultimately only, question we face is the degree to which Stamps retains precedential value after the Supreme Court's decision in Lohr.

A

To resolve the impact of Lohr on our precedent in Stamps, we begin by setting out the relevant statutory and regulatory language that we must consider. Section 360k(a) ("General Rule") is the preemption provision of the MDA governing the extent to which the MDA preempts state law. It

applies both to situations arising under the § 510(k) process and the PMA process. It states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The FDA has promulgated regulations interpreting § 360k, which state:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.

21 C.F.R. § 808.1(d).

B

With both the statute and the regulations in mind, we turn to consider the intervening Supreme Court decision, Medtronic Inc. v. Lohr, 518 U.S. 470. In Lohr, the Supreme Court considered whether state tort claims were preempted when the FDA subjected the medical device to § 510(k) notification under the MDA, a process, as we have noted, far

less thorough than the PMA process presented in this case.[4] In a five to four decision, the Court held that the state tort claims in that § 510(k) case were not preempted. The Court, however, fractured over the question of whether the preemption section of the MDA would ever preempt general state law tort claims.

The facts underlying the plaintiffs' claims in Lohr are similar to the facts in our case: Lohr and her husband sued on state law claims over a defective lead in a pacemaker. Their complaint alleged both negligence and strict liability claims for defective design, failure to warn, and negligent manufacturing. Unlike our case, however, which involves a rigorous review under the PMA process, Medtronic began marketing the pacemaker lead in Lohr after the FDA had found only that the device was "substantially equivalent" to devices already on the market under § 510(k). Indeed, the FDA itself "emphasized ... that [the § 510(k) notification process] should not be construed as an endorsement of the pacemaker lead's safety." Lohr, 518 U.S. at 480.

The Court's reasoning largely focused on the requirements of the FDA's regulation interpreting § 360k, cited

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[4]As the Supreme Court itself has observed, the PMA process and the § 510(k) process are clearly distinguishable. See Lohr, 518 U.S. at 493 (noting that substantially equivalent devices have "never been formally reviewed under the MDA for safety or efficacy" and that the FDA does not consider the § 510(k) process "official FDA approval"); Buckman, 121 S.Ct. at 1017 ("Admittedly, the § 510(k) process lacks the PMA review's rigor: The former requires only a showing of substantial equivalence to a predicate device, while the latter involves a time-consuming inquiry into the risks and efficacy of each device.").

and quoted earlier in this opinion. The Court observed that certain factors must be present, according to the regulations, before § 360k would preempt state requirements. First, there must be a state requirement specifically developed with respect to medical devices that is different from or in addition to federal requirements. Second, the state requirement must relate to the safety or effectiveness of the device, or "'other matter included in a requirement applicable to the device.'" Lohr, 518 U.S. at 500 (quoting 21 U.S.C. § 360k(a)). State requirements of "'general applicability' are not preempted except where they have 'the effect of establishing a substantive requirement for a specific device.'" Id. Third, the federal requirement must be specific to the particular device. The Court held that because neither the federal requirements relating to the § 510(k) notification procedure nor the state common law requirements were specific to the device, Lohr's tort claims were not preempted.

Although the Court concluded that Lohr's tort claims were not preempted, the majority split on the broader question of whether the duties enforced by common law actions could ever be "requirements" for the purpose of preemption. The four justice plurality written by Justice Stevens, distinguishing the MDA from the statute in Cipollone v. Liggett Group, Inc., 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992), found that general common law actions were not the "requirements" that Congress was concerned about when it enacted the preemption provision. Thus, Justice Stevens concluded that "§ 360k(a) simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." Lohr, 518 U.S. at 491. That, however, was only a plurality.

The meaning of Lohr as applied to our case becomes confusing at this point. Concurring with only parts of the

majority writing, Justice Breyer found that the MDA could in fact preempt state tort suits. Relying on Cipollone, in which the "Court made clear that similar language 'easily' encompassed tort actions," he reasoned that a state requirement that takes the form of a duty of care is essentially no different from a state statute or regulation. Id. at 504 (Breyer, J., concurring). Justice Breyer noted, however, that the FDA promulgated a regulation that allows preemption when there are "'specific [federal] requirements applicable to a particular device.'" Id. at 506 (quoting 21 C.F.R. § 808.1(d) (1995)). Because the FDA requirements relating to design, manufacturing and labeling in the § 510(k) notification process at issue in Lohr were "not 'specific' in any relevant sense," Justice Breyer concluded that the FDA did not intend the § 510(k) notification procedures to preempt state tort claims. Id. at 507.

The four justices concurring in part and dissenting in part, relying on the § 360k preemption language and not the FDA's regulations, concluded that "state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA." Id. at 509 (O'Connor, J., concurring in part, dissenting in part). Justice O'Connor noted that a majority of the Court in Cipollone agreed that state common law damages actions do impose "requirements," and that the rationale behind that decision was equally applicable in Lohr. Id. at 510. Thus, given Justice Breyer's concurrence, five justices would agree that state common law actions do impose "requirements" that can be preempted under the statute, as found in Cipollone.

Because only parts of Justice Stevens's opinion commanded a majority, extracting the final meaning of Lohr is no easy task. Assessing Lohr in the light of the three requirements for preemption described above, the Court first held that general common law duties do not impose

requirements that are different from or in addition to the § 501(k) process. The Court offers no clear guidance on when the common law may satisfy the second factor, that is, that the state requirement relate to the safety or effectiveness of the device or establish a "substantive requirement" for a specific device. Although Justice Breyer's concurrence very specifically disavows the view that common law duties cannot provide substantive requirements for the purpose of preemption, neither his concurrence nor the plurality opinion offers much help to us in developing the point. As to the third factor, the Court held that the FDA's "substantially equivalent" determination under the § 501(k) process is not a federal regulation specific to a particular device, at least under the facts of Lohr. Because these holdings do not explicitly or implicitly decide the case before us, we must compare Lohr with Stamps, the circuit precedent that we are required to follow.

C

Our decision in Stamps, 984 F.2d 1416, which relies on Cipollone and predates Lohr, held that state tort claims in that case were preempted under the MDA. In Stamps, the plaintiff contracted a rare autoimmune disease from being injected with defendant's Class III products. She then filed suit alleging defective design, inadequate warnings, and negligent failure to warn. Because the FDA scrutinized the labeling, design, and manufacturing of a product during the PMA process, we determined that each of these state claims covered an area stringently regulated by the FDA.

We then addressed the question of whether state tort claims could be considered state "requirements" under § 360k. Relying on the Supreme Court's preemption doctrine as laid out in Cipollone, 505 U.S. 504, we noted that the term "requirements" in § 360k(a) "'sweeps broadly' and encompasses

common law tort actions within its preemptive scope." Stamps, 984 F.2d at 1421. Thus, the specific duties in Texas tort liability create requirements in addition to the strict requirements of the Class III PMA process. Stamps concluded that "[s]tate tort causes of action--to the extent they relate to safety, effectiveness, or other MDA requirements--constitute requirements 'different from, or in addition to' the Class III process; they are, therefore, preempted." Stamps, 984 F.2d at 1424.

III

When we turn to consider the impact of Lohr on the precedential effect of Stamps, we can immediately conclude that the Supreme Court did not explicitly overrule the case. Neither do we think that Lohr implicitly requires us to disregard Stamps as controlling precedent.[5] Although Stamps gave § 360k a

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[5]In fact, after Lohr, both the Sixth and the Seventh Circuits determined that the PMA process constitutes specific federal requirements that preempt state tort suits. Kemp v. Medtronic, 231 F.3d 216, 226-227 (6th Cir. 2000); Mitchell v. Collagen Corp., 126 F.3d 902, 913 (7th Cir. 1997). These decision parallel our reasoning in Stamps. Although not all courts have found that common law tort suits relating to the device are preempted by the PMA process, see Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999) (finding that plaintiffs' state law tort claims were not preempted by Medtronic's compliance with the FDA's PMA process), Brooks v. Howmedica, Inc., 236 F.3d 956 (8th Cir. 2001) (finding that the PMA process constitutes specific federal requirements and common law tort suits can constitute specific state requirements but finding no conflict between them), vacated and reh'g en banc granted by 246 F.3d 1149 (8th Cir. 2001), our question is

somewhat broader preemptive scope than the Supreme Court's opinion in Lohr,[6] none of the components of the preemption test in Lohr contradict the holding in Stamps as applied here. As noted above, the Supreme Court held that for preemption under § 360k, there must be a state requirement--which does not exclude common law tort duties--with respect to a medical device that relates to the safety or efficiency of a device, or establishes a substantive requirement for the device, that is different from or in addition to a specific federal requirement. Lohr, 518 U.S. at 500. Stamps is not contrary to these criteria.

A

First, Stamps found that common law tort suits can impose state requirements for the purposes of preemption. Stamps, 984 F.2d at 1423. Although not part of the holding of Lohr, a majority of the justices in Lohr clearly agreed with this proposition. See 518 U.S. at 509 ("I conclude that state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ

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not whether the panel in Stamps correctly decided the case, but whether the Supreme Court overruled Stamps. As long as Stamps is not inconsistent with the law set out in Lohr, this panel has no authority to overrule it.

[6] For instance, Stamps notes that "section 360(k). . . 'sweeps broadly' and encompasses common law tort actions within its preemptive scope." Stamps, 984 F.2d at 1421. In contrast, Lohr remarks on the FDA's "narrow understanding" of § 360k and finds that "it is impossible to ignore [the statutory and regulatory language's] overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." Lohr, 518 U.S. at 500, n. 18.

from those imposed by the FDCA")(O'Connor, J., dissenting). Id. at 503 ("[T]he MDA will sometimes pre-empt a state-law tort suit.")(Breyer, J., concurring). Thus, it seems clear that Lohr did not overrule our holding in Stamps that state tort suits can constitute specific state requirements for the purposes of preemption.

B

Second, Stamps found that common law duties could be preempted "to the extent that they relate[d] to safety, effectiveness, or other MDA requirements." Stamps, 984 F.2d at 1423. With some similarity, Lohr observed that state requirements must, "with respect to" medical devices, establish a "substantive requirement for a specific device," and must relate to the "safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." Lohr, 518 U.S. at 500. The Lohr majority opinion did not articulate when common law requirements may become "substantive requirements" or under what circumstances they are considered to be "specifically developed 'with respect to' medical devices." Id. at 501. To determine whether Stamps's understanding of common law duties as state requirements is consistent with Lohr, we must therefore consider Justice Stevens's opinion in the light of Justice Breyer's concurrence.

Justice Breyer joined in the majority's finding that "general state common-law requirements in this suit were not specifically developed 'with respect to' medical devices," and that "these state requirements escape preemption . . . because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers." Lohr, 518 U.S. at 501. Justice Breyer's separate concurrence, however, which recognizes that common law tort suits may be preempted, does not support a conclusion

that common law claims are invariably too general for preemption. Indeed, Justice Breyer noted that he "basically agree[d] with Justice O'Connor's discussion" of whether the MDA can preempt a state law tort suit Id. at 503, which observed that "state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA." Id. at 509. Furthermore, Justice Breyer specifically disavowed the portions of the opinion finding that "[i]t will be rare indeed for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device,'" Id. at 502 (plurality) (citing CFR § 808.1(d)(6)(ii)(1995)), and that the term "'[r]equirement appears to presume that the State is imposing a specific duty on the manufacturer." Id. at 487. As noted by the Ninth Circuit, these apparently conflicting positions make analysis difficult:

> [I]t makes little sense to argue that Justice Breyer would write separately to make clear his position that duties arising under state common law can constitute state law "requirements" which can be preempted by the MDA, and then agree that because tort law consists of generally applicable principles, it is always preempted, even in the face of specific federal requirements.

Papike v. Tambrands Inc., 107 F.3d 737, 742 (9th Cir. 1997).

Of course, we are plainly bound to follow the majority opinion in Lohr; yet, we cannot fully grasp the opinion's interpretation of when state common law requirements are considered "specifically developed with respect to medical devices" without Justice Breyer's concurrence. The majority opinion says that general common law obligations are not a threat to federal requirements. Id. at 501. Justice Breyer joins in the opinion, but, in his concurrence, he points out that these

general common law requirements are not a threat because there is no potential for them to conflict with the federal requirements at issue in Lohr, namely, the requirements under the § 501(k) process. He also notes that while common law duties may seem general, they can result in the imposition of standards that are very device-specific. Justice Breyer takes the position that there is no preemption in Lohr because there is no conflict between the § 501(k) process and general common law duties. See Lohr, 518 U.S. at 508 (Breyer, J., concurring)("I can find no actual conflict between any federal requirement and any of the liability-creating premises of the plaintiffs' state-law tort suit"). Justice Breyer's emphasis on the juxtaposition of the state and federal duties suggests that the Court would be less sanguine about the generality of common law duties if the federal requirements were specific, say, as in the PMA process.[7]

We think it is important to read the portion of the majority opinion addressing specific state requirements narrowly to avoid adopting as controlling law the broadly worded plurality opinion. Using Justice Breyer's concurrence as a guide, we can conclude only that general duties of care can generate specific requirements that conflict with specific FDA requirements. We read Justice Breyer's special concurrence to

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[7]Justice Breyer even notes that "it is possible that the plurality also agrees" that

> insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action.

Lohr, 518 U.S. at 504-05 (Breyer, J. concurring). This observation suggests that it was important to Lohr's conclusion that both state and federal requirements were general.

recognize that, although a manufacturer's general duty of care to avoid foreseeable dangers may be too general to merit preemption when there is no specific federal requirement, the proof required to establish a particularly alleged common law claim can be specific enough that the claim becomes preempted as an "additional" or "different" requirement than the FDA requirement.[8] This reasoning is consistent with the majority opinion; while the general duty, standing on its own, is not a threat to federal requirements and is not developed specifically "with respect to" medical devices, the elements needed to prove a violation of that general duty may be very specifically tailored to the device, and the state court action may therefore threaten specific federal requirements. Because the federal § 510(k) requirements were not specific, it was unnecessary in Lohr to reach that conflict. For instance, as an example of a general common law duty, the majority opinion uses a "general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use." Id. at 501. While this duty does not seem "developed with respect to" a medical device specifically, proving a violation of that duty would require a jury to determine precisely what information users should have been provided. Those determinations would not conflict with the § 510(k) process, because that process does not determine or approve what information consumers of the product should be provided. On the other hand, however, a jury's determination may directly conflict with FDA determinations and approvals made during the PMA review process.

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[8]However, common law duties that incorporate the PMA process, such as the general duty to take due care to comply with the PMA process in labeling or manufacturing, will never contain specific requirements that are additional to or different from federal requirements. Therefore, claims based on those duties are not preempted. See Lohr, 518 U.S. at 495.

Thus, reading the language in the majority opinion through the lens of Justice Breyer's concurrence, we cannot say that Lohr overruled the holding of Stamps that common law tort claims challenging the safety or effectiveness of a device create specific requirements under state law. After Lohr, however, we need to consider more than whether the common law duties relate to safety, effectiveness, or other MDA requirements; we need to focus on whether the specific requirements imposed by those common law duties threaten to interfere with specific federal requirements.

C

Third, Stamps interpreted state tort causes of action as requirements "different from, or in addition to" the PMA process, thereby meriting preemption. Stamps, 984 F.2d at 1423. This holding reflects a comparison of state and federal requirements and a consideration of how additional state common law requirements could undermine the FDA's detailed PMA review process. On the other hand, Lohr compared common law duties with the § 510(k) process, which imposes relatively minor disclosure requirements, and found that preemption was not appropriate. Given the difference between the intensive PMA review and the minimal requirements under the § 510(k) process, Lohr does not call into question the holding of Stamps, that common law duties can impose requirements different from or in addition to the PMA process.

Stamps, however, specifically disagreed with the proposition that "the lack of direct conflict between the state and federal regulations compel[led] a finding of no preemption." Id. at 1424. On the other hand, this proposition seems to have been adopted by the Supreme Court; Lohr notes that "[n]othing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when

those duties parallel federal requirements." Lohr, 518 U.S. at 495. This language tells us that tort suits based on a manufacturer's failure to follow the FDA's regulations and procedures are not preempted. Indeed, that is precisely what the district court held in this case, and that holding has not been appealed. In the context of the PMA process, we agree that state tort suits that allege, as the basis of their claim, that the approved FDA requirements have not been met are not preempted. Thus, Lohr narrows the language in Stamps's preemption analysis to allow for state actions that parallel federal requirements. This holding of Lohr, although overruling Stamps in that specific matter, does not, however, overrule Stamps as it applies to the case before us.

D

Fourth, Stamps held that the PMA process imposed specific federal requirements as to labeling, manufacturing, and design for the purposes of preemption.[9] Here, too, there is no conflict with Lohr. Although Lohr considered the application of the identical FDA regulation governing labeling, the labeling requirements in Lohr under the § 510(k) process were general; as it did not go through the PMA process, the labeling in Lohr was not specifically reviewed by the FDA.

On its face, therefore, Lohr is limited to a finding that

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[9]During the PMA process, the FDA reviews the proposed labeling as well as the ingredients, components, methods, controls, and facilities used in the manufacture and processing of the device. 21 U.S.C. § 360e(c)(1)(B)-(C),(F). If any element of the manufacturing does not comply with regulations, or labeling is found to be false or misleading, the application for approval is denied. Id. § 360e(d)(2)(A)-(D).

the § 501(k) process does not create specific federal requirements that conflict with state tort actions. Indeed, the plurality's opinion itself seems to leave this suggestion when it notes at several points in the course of its writing the very significant differences between the FDA's § 510(k) approval and a PMA approval. See, e.g., 518 U.S. at 492-94 (noting that the § 510(k) process "is focused on equivalence, not safety. As a result, substantial equivalence determinations provide little protection to the public") (internal quotations and citations omitted).[10] The PMA is specifically focused on safety and requires a significant weighing of considerations specific to the device before approval is granted. Thus, the fact that the § 510(k) process did not preempt state causes of action in Lohr does not indicate that the PMA process cannot preempt state tort causes of action.

Thus, for all these reasons, we are fully convinced that Stamps has not been overruled and remains viable authority in this circuit to the extent that we have described. Instead of overruling Stamps, Lohr should be read to implicitly affirm our holding in Feldt v. Mentor Corp., 61 F.3d 431 (5th Cir. 1995), in which we reached the same conclusion as did the Court in Lohr, that the § 510(k) process did not create preemptive "requirements." 518 U.S. at 484 n.6.[11] We think that our separate preemption treatment of the differing processes to

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[10]See also id. at 480 ("The agency emphasized, however, that this determination [of substantial equivalence] should not be construed as an endorsement of the pacemaker lead's safety.").

[11]Our decision in Feldt explicitly discusses our decision in Stamps, 61 F.3d at 435, but, after analyzing the § 510(k) process, states, "there are, in short, no requirements or prohibitions specifically regarding the design of non-PMA Class III devices." Id. at 438.

device approval is further reflection and acknowledgment of the fact that the PMA process is of an order that is a magnitude apart from § 510(k) approval.

In sum, we simply cannot read Lohr as establishing a new rule of law that contradicts our preexisting case law as it applies in this appeal. Thus, although the broad holding of Stamps that the PMA process preempts state tort causes of action to the extent that they relate to safety, effectiveness or other MDA requirements is narrowed by Lohr's finding that preemption requires substantive requirements imposed by common law duties to threaten federal requirements, Stamps remains controlling precedent for the purpose of this appeal.

IV

We turn now to apply Stamps, as narrowed by Lohr, to the case before us. The plaintiffs allege that Medtronic breached state law duties by designing a pacemaker lead that contained certain materials, by labeling the lead with certain warnings, and by manufacturing the lead in a certain way. The design of the lead, the labeling on the lead, and the manner of manufacturing of the lead were all submitted to the FDA in great detail and approved by the FDA in the PMA process. Like the inadequate labeling, failure to warn, and defective design claims in Stamps, the plaintiffs' claims that the district court found to be preempted relate to areas specifically covered in the PMA process, and seek to impose requirements that are different from and, indeed, conflict with the PMA process.

The district court specifically found those claims that paralleled the federal process--the claims that Medtronic did not adequately comply with the PMA process--were not preempted under § 360k. This finding comports with Lohr, that general duties of care that parallel federal requirements are not

"different from, or in addition to" federal requirements, and are therefore not preempted. In Stamps, our circuit spoke to the precise question presented in this appeal. And we have concluded here that the Supreme Court's fractured ruling in Lohr does nothing to upset Stamps's binding authority as respects this particular appeal. We therefore reaffirm that a medical device manufacturer's compliance with the FDA's PMA process will preempt state tort law claims brought with respect to that approved device and relating to safety, effectiveness or other MDA requirements when the substantive requirements imposed by those claims potentially conflict with PMA approval. Thus, the plaintiffs' tort law claims relating to design, manufacturing process, and failure to warn are preempted by the MDA.

V

For the reasons stated above, the judgment of the district court is

AFFIRMED.

THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

BILLYE JEANNE MARTIN

V.

MEDTRONIC, INC.

CA. NO. C-96-495

ENTERED August 8, 1999

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Billye Jeanne Martin sued Defendant Medtronic in state court claiming that a ventricular lead in a pacemaker manufactured by Defendant failed after implantation and that Plaintiff suffered damages as a result. After removing the case to this Court, Defendant moved for summary judgment that Plaintiff's claims were preempted by § 360k of the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act. 21 U.S.C. § 360k. For the following reasons, the Court grants in part and denies in part Defendant's motion for summary judgment.

JURISDICTION

Plaintiff originally sued both Medtronic and Diagnostic

Center Hospital, Inc., the hospital at which the allegedly defective pacemaker was implanted. There was some confusion at the time the case was removed as to whether Diagnostic was domiciled in Texas, a fact which if true, would destroy diversity jurisdiction. The question became moot when Plaintiff moved to dismiss her case against Diagnostic, and the Court granted the motion. It is well-settled that a district court or appellate court may dismiss a non-indispensable party and preserve diversity jurisdiction. Newman-Green, Inc. v. Alfonzo-Lorrain, 109 S.Ct. 2218, 2223 (1989). Because diversity jurisdiction exists, the Court declines to rule on the unsettled question of whether the MDA completely preempts Plaintiffs state law claims and makes them removable to federal court. See Strong v. Telectronics Pacing Systems, Inc., 78 F.3d 256 (6th Cir. 1996) (no complete preemption); Richardson v. Advanced Cardiovascular Systems, Inc., 865 F. Supp. 210 (E.D.La. 1994) (finding complete preemption).

FACTS

A pacemaker manufactured by Medtronic was implanted in Plaintiff on December 3, 1989. On August 29, 1994, Plaintiff began to feel lightheaded and faint. Testing revealed a failure of the ventricular lead, a part of the pacemaker which is designed to transmit small electrical pulses to the heart from a pacemaker pulse generator and return signals from the heart to the pulse generator. The type of ventricular lead used in this particular pacemaker was known as a Model 4004. Plaintiff has stipulated that her lawsuit involves only alleged defects in the Model 4004 lead.

The Court finds that the Model 4004 lead received pre-market approval (PMA) from the FDA. This is the most rigorous scrutiny that a product can undergo at the FDA. The process began on March 26, 1982, when Medtronic submitted

an Investigatory Device Exemption application to the FDA requesting permission to clinically investigate the Model 4003 lead, which is similar to the Model 4004 lead.[1] This application was granted, and the investigation was conducted over four years. On September 30, 1983, Medtronic submitted a PMA application to the FDA for the Model 4003, and this was approved on July 26, 1986.

The information that was reviewed by the FDA included the results of all tests which had been performed on the Model 4003, including animal testing. Also included were engineering drawings of the device and a description of the manufacturing process that would be used. Finally, the application contained all of the proposed product labels, technical manuals and package labeling which were to be distributed with the Model 4003.

On July 18, 1988, Medtronic applied for pre-market approval of the Model 4004 lead as a supplemental application to the PMA used for the Model 4003. The PMA supplement included much of the same information which was included in the PMA for the Model 4003. The supplement stated that human testing was not necessary for the Model 4004 because animal testing had already demonstrated performance equivalent to the Model 4003, for which human tests had already been submitted. The FDA approved the Model 4004 PMA supplement on February 10, 1989.

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[1]The main difference is that the Model 4004 lead is bipolar. In addition, the Model 4004 has thicker insulation and several other modifications which are described in the affidavit of Charles Swanson. See Defendant's Motion for Summary Judgment.

Although Plaintiff contests that this process constituted an approval by the FDA of the design and manufacturing processes for the Model 4004 lead, she has come forth with no evidence to support this assertion. Defendant has presented an affidavit and numerous letters from the FDA to support its assertion that the Model 4004 lead received full PMA review. In light of this evidence, the Court finds that Plaintiff has failed to demonstrate any genuine factual dispute. The Court therefore finds that the Model 4004 lead received full PMA review and that its design, labeling, and manufacturing processes were approved by the FDA.

DISCUSSION

1. THE PREEMPTIVE EFFECT OF THE MDA

The Medical Device Amendments were added to the Food, Drug, and Cosmetics Act in 1976 in order to allow the FDA to regulate medical devices. The strictest FDA regulation is reserved for Class III devices which are defined as devices which: (1) are to be used for supporting or sustaining human life or that are of substantial importance in preventing impairment of public health, or (2) present a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II). In order to market a Class III device in the United States, the manufacturer must obtain pre-market approval from the FDA, which requires "reasonable assurances of [the product's] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C).[2] There is an

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[2]The PMA process involves a rigorous review of the ingredients, components, manufacturing methods, and proposed labeling of a medical device. 21 U.S.C. § 36Oe(c)(1)(A)-(G). The average time required for review is approximately 1200 hours. Fry v. Allergan Medical Optics, et al., 695 A.2d 511, 513

exception for devices which were already on the market when the MDA was passed, 21 U.S.C. § 36Oe(b)(1)(A), as well as devices which are substantially equivalent to those devices (the § 510k exception). 21 U.S.C. § 360e(b)(1)(B).

The MDA contains a clause which preempts certain areas of state law relating to medical devices:

> ...no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The FDA implemented a regulation interpreting this preemption clause, which a majority of the Supreme Court in Medtronic, Inc. v. Lohr, 116 S.Ct. 2240, 2256 (1996) found to be entitled to substantial weight:

> State or local regulations are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not

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(R.I. 1997).

> preempted by [the act's preemption clause] because they are not 'requirements applicable to a device' within the meaning of [the preemption clause]. The following are examples of State or local requirements that are not regarded as preempted by [the preemption clause]:
> (1) [The preemption clause] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g. requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or unfair trade practices in which the requirements are not limited to devices.
> (2) [The preemption clause] does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

21 C.F.R. § 808.1(d).

In Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir. 1993), the Fifth Circuit held that the MDA preempted state law claims for defective design, inadequate warnings, and negligent failure to warn with respect to collagen implants which had undergone PMA review. The court found that the FDA scrutinizes the labeling, design, and manufacturing of a product during the PMA process, and that the plain language of the MDA preempts state law tort suits which would impose requirements different from those imposed by the FDA.

In 1996, the Supreme Court decided Medtronic, Inc. v. Lohr, 116 S.Ct. 2240 (1996), and shed some light on the preemptive effect of the MDA. The Court held that state law claims against Medtronic for an allegedly defective pacemaker were not preempted by the MDA. Importantly, the pacemaker at issue in that case, unlike the one currently before this Court, had not undergone full PMA review. The pacemaker in Lohr

was deemed substantially equivalent to a pacemaker already on the market when the MDA was enacted, so it was approved by the FDA under the far less rigorous § 510k exception.

The Lohr decision settled some issues. At least five Justices agreed that state law tort actions are "requirements" which the MDA can potentially preempt. 116 S.Ct. at 2259, 2262. The Court was unanimous that because the § 510k procedure says nothing about a product's safety, the FDA's § 510k approval of a product does not preempt a state law claim that the product is defectively designed. Id. at 2254, 2263-64. A majority of the Court also held that FDA Good Manufacturing Practices and labeling requirements are not sufficiently specific and do not relate only to medical devices, so they do not preempt state law claims for manufacturing defects and failure to warn. Id. at 2258. Finally, the Court was unanimous that claims for products manufactured in *violation* of FDA requirements are not preempted. Id. at 2255, 2264.

The Lohr case does not address the situation before this Court in which the allegedly defective product received the more rigorous PMA scrutiny from the FDA. This Court finds that the Lohr case is distinguishable, because as a majority of the Court stated: "[t]he 510(k) process is focused on *equivalence*, not safety." 116 S.Ct. at 2254. The PMA process is focused on safety -- PMA means that the FDA has received "resonable assurance" that a device is both safe and effective. 21 U.S.C. § 360c(a)(1)(C). Although a count of the positions of Supreme Court Justices from the concurrence and dissent is not binding, this Court also notes that at least five Justices would likely support the preemption of state law concerning a device which had gone through the PMA process.

Nearly all courts which have considered the issue in the wake of Lohr have agreed with this position. See Martin v.

Telectronics Pacing Systems, Inc., 105 F.3d 1090 (6th Cir. 1997) (state law products liability and misrepresentation claims concerning an allegedly defective pacemaker were preempted by MDA where pacemaker had received investigational device exemption {IDE), requiring a process similar but not identical to PMA); Chambers v. Osteonics Corp., 109 F.3d 1243 (7th Cir. 1997) (strict liability and breach of implied warranty claims concerning prosthetic hip which had received IDE were preempted, but claim that the manufacturer did not follow approved FDA procedures was not preempted); Berish v. Richards Medical Co., 937 F. Supp. 181 (N.D.N.Y. 1996) (same); Arthur Fry v. Allergan Medical Optics, et al., 695 A.2d 511 (R.I. 1997} (claims for allegedly defective intraocular lens implant which had undergone PMA review were preempted); Green v. Dolsky, 685 A.2d 110 (Pa. 1996) (same holding for collagen implants); but see Rodriguez-Suris v. Montesinos, 935 F. Supp. 71, 75 n.3 (D. Puerto Rico 1996).

The Court therefore follows pre-Lohr Fifth Circuit precedent, the implication from Lohr, and the vast majority of cases decided since Lohr, and holds that § 360k of the MDA preempts some state claims brought against the manufacturers of products which have obtained PMA from the FDA. The remaining question is which claims are preempted.

II. PLAINTIFF'S CAUSE OF ACTION

At a hearing on August 5, 1997, Plaintiff represented to the Court that she had three causes of action: (1) a claim that the pacemaker lead was unreasonably dangerous as designed; (2) a claim that the pacemaker lead was unreasonably dangerous as manufactured; and (3) a claim that Medtronic breached an implied warranty that the lead was safe and fit for the purposes for which it was intended. The Court notes that Plaintiff's original complaint makes several other claims, including a claim

for negligent failure to warn.

The Court finds that any claim challenging the design of the Model 4004 ventricular lead is preempted by § 360k and the pre-market approval of the lead by the FDA. The rigorous PMA process certainly constitutes a specific federal requirement relating to the design of the lead, and allowing a state common law suit challenging that design to go forward could impose additional and even inconsistent requirements.

The Court also finds that any claim in which the Plaintiff challenges the manufacturing processes which were approved by the FDA is preempted. Although the Court notes that the Lohr Court held that general Good Manufacturing Practices were not sufficiently specific to preempt manufacturing defect claims, here the FDA approved specific manufacturing plans as part of the PMA process. Similarly, the Court finds that any claim in which the Plaintiff challenges the adequacy of the warnings which were approved by the FDA is preempted. Although general labeling requirements are not enough to create federal preemption, here the FDA specifically approved the packaging, labels, and supplemental materials which were to accompany the lead. In fact, any change in the manufacturing or labeling that could effect the Model 4004 lead's safety and effectiveness would have required prior FDA approval. 21 U.S.C. § 36Oe(e)(1)(B),(E); 21 C.F.R. § 814.39(a).

The claims described above are preempted whether they are couched in terms of products liability, breach of warranty, negligence, gross negligence, or state law deceptive trade practices. This does not mean that all potential claims are preempted. For example, Plaintiff could claim that the manufacturing processes, specifications, or materials actually used by Medtronic were not the same as those that were approved by the FDA. The Court therefore grants the parties

120 days to conduct discovery in order to determine whether Plaintiff wishes to press any non-preempted claims.

CONCLUSION

For these reasons the Court grants in part and denies in part Defendant's motion for summary judgment. The parties are granted 120 days to conduct further discovery in order to determine whether any viable claims remain.

ORDERED this 8 day of August, 1997.

H. W. HEAD, JR.
UNITED STATES DISTRICT JUDGE

THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

BILLYE JEANNE MARTIN

V.

MEDTRONIC, INC.

CA. NO. C-96-495

ENTERED August 27, 1999

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND DENYING PLAINTIFF'S MOTION FOR RECONSIDERATION

This is a products liability suit. Jurisdiction is proper in the Court because there is complete diversity of the parties, 28 U.S.C. 1332.

Plaintiff claims she was injured when a Model 4004M ventricular lead in a pacemaker manufactured by defendant failed after implantation. Defendant moved for summary judgment on the grounds that plaintiff's claims are preempted by § 360k of the Mdeical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act, 21 U.S.C. § 360k. The Court granted in part and denied in part defendant's motion because the device in question received full pre-market approval (PMA) from the FDA and, therefore, § 360k preempted some, but not all, of plaintiff's potential claims. Specifically, the Court noted

that "[p]laintiff could claim that the manufacturing processes, specifications, or materials actually used by [defendant] were not the same as those approved by the FDA," and granted additional time to conduct discovery and determine whether non-preempted claims existed. Plaintiff has not offered evidence that the processes, specifications, or materials defendant used in manufacturing the Model 4004M ventricular leads differed from the approved processes, specification, or materials. Accordingly, the Court grants defendant's renewed motion for summary judgment on this remaining issue.

In her Memorandum Brief, plaintiff suggests the Court reconsider and find her claims are not preempted by the MDA, set aside its order granting partial summary judgment, and schedule this case for trial on all claims. Plaintiff argues the Court should withdraw its previous order granting defendant's motion for summary judgment because of the United States Court of Appeals for the Eleventh Circuit's recent decision in *Goodlin v. Medtronic Inc.*, 167 F.3d 367 (11th Cir. 1999). The Eleventh Circuit found 21 U.S.C. § 360(k) does not preempt state law claims based on the failure of Medtronic Model 4004M ventricular leads. *Goodlin v. Medtronic Inc.*, 167 F.3d 1367, 1377 (11th Cir. 1999). In *Goodlin*, the Eleventh Circuit's decision was based on its finding that the PMA process did not impose specific federal requirements. Id. at 1373-1377. The Fifth Circuit has held to the contrary. *See Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421-23 (5th Cir. 1993), *cert. denied*, 114 S.Ct. 86 (1993). The Seventh Circuit has also concluded that the PMA process imposes specific federal requirements. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997), *cert denied*, 118 S.Ct. 1300 (1998). The Court follows the Fifth Circuit's conclusion in *Stamps* and the Seventh Circuit's conclusion in *Mitchell*. Accordingly, the Court denies plaintiff's motion for reconsideration.

ORDERED this 25 day of August, 1999.

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H. W. HEAD, JR.
UNITED STATES DISTRICT JUDGE

THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

LIRBA SALAZAR

V.

MEDTRONIC, INC.

CA. NO. C-96-425

ENTERED August 8, 1999

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Lirba Salazar sued Defendant Medtronic in this Court claiming that a ventricular lead in a pacemaker manufactured by Defendant failed after implantation and that Plaintiff suffered damages as a result. Defendant moved for summary judgment that Plaintiff's claims were preempted by § 360k of the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act. 21 U.S.C. § 360k. For the following reasons, the Court grants in part and denies in part Defendant's motion for summary judgment.

JURISDICTION

The Court has diversity jurisdiction over this case pusuant to 28 U.S.C. § 1332. Because diversity jurisdiction

exists, the Court declines to rule on the unsettled question of whether the MDA completely preempts Plaintiff's state law claims and makes them removable to federal court. See Strong v. Telectronics Pacing Systems, Inc., 78 F.3d 256 (6th Cir. 1996) (no complete preemption); Richardson v. Advanced Cardiovascular Systems, Inc., 865 F. Supp. 210 (E.D.La. 1994) (finding complete preemption).

FACTS

A pacemaker manufactured by Medtronic was implanted in Plaintiff in 1990. Plaintiff alleges that the pacemaker was defective, and that she suffered personal injuries as a result. Testing revealed a failure of the ventricular lead, a part of the pacemaker which is designed to transmit small electrical pulses to the heart from a pacemaker pulse generator and return signals from the heart to the pulse generator. The type of ventricular lead used in this particular pacemaker was known as a Model 4004. Plaintiff has stipulated that her lawsuit involves only alleged defects in the Model 4004 lead.

The Court finds that the Model 4004 lead received pre-market approval (PMA) from the FDA. This is the most rigorous scrutiny that a product can undergo at the FDA. The process began on March 26, 1982, when Medtronic submitted an Investigatory Device Exemption application to the FDA requesting permission to clinically investigate the Model 4003 lead, which is similar to the Model 4004 lead.[1] This application

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[1]The main difference is that the Model 4004 lead is bipolar. In addition, the Model 4004 has thicker insulation and several other modifications which are described in the affidavit of Charles Swanson. See Defendant's Motion for Summary Judgment.

was granted, and the investigation was conducted over four years. On September 30, 1983, Medtronic submitted a PMA application to the FDA for the Model 4003, and this was approved on July 26, 1986.

The information that was reviewed by the FDA included the results of all tests which had been performed on the Model 4003, including animal testing. Also included were engineering drawings of the device and a description of the manufacturing process that would be used. Finally, the application contained all of the proposed product labels, technical manuals and package labeling which were to be distributed with the Model 4003.

On July 18, 1988, Medtronic applied for pre-market approval of the Model 4004 lead as a supplemental application to the PMA used for the Model 4003. The PMA supplement included much of the same information which was included in the PMA for the Model 4003. The supplement stated that human testing was not necessary for the Model 4004 because animal testing had already demonstrated performance equivalent to the Model 4003, for which human tests had already been submitted. The FDA approved the Model 4004 PMA supplement on February 10, 1989.

Although Plaintiff contests that this process constituted an approval by the FDA of the design and manufacturing processes for the Model 4004 lead, she has come forth with no evidence to support this assertion. Defendant has presented an affidavit and numerous letters from the FDA to support its assertion that the Model 4004 lead received full PMA review. In light of this evidence, the Court finds that Plaintiff has failed to demonstrate any genuine factual dispute. The Court therefore finds that the Model 4004 lead received full PMA review and that its design, labeling, and manufacturing

processes were approved by the FDA.

DISCUSSION

1. THE PREEMPTIVE EFFECT OF THE MDA

The Medical Device Amendments were added to the Food, Drug, and Cosmetics Act in 1976 in order to allow the FDA to regulate medical devices. The strictest FDA regulation is reserved for Class III devices which are defined as devices which: (1) are to be used for supporting or sustaining human life or that are of substantial importance in preventing impairment of public health, or (2) present a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II). In order to market a Class III device in the United States, the manufacturer must obtain pre-market approval from the FDA, which requires "reasonable assurances of [the product's] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C).[2] There is an exception for devices which were already on the market when the MDA was passed, 21 U.S.C. § 36Oe(b)(1)(A), as well as devices which are substantially equivalent to those devices (the § 510k exception). 21 U.S.C. § 360e(b)(1)(B).

The MDA contains a clause which preempts certain areas of state law relating to medical devices:

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[2]The PMA process involves a rigorous review of the ingredients, components, manufacturing methods, and proposed labeling of a medical device. 21 U.S.C. § 36Oe(c)(1)(A)-(G). The average time required for review is approximately 1200 hours. Fry v. Allergan Medical Optics, et al., 695 A.2d 511, 513 (R.I. 1997).

> ...no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The FDA implemented a regulation interpreting this preemption clause, which a majority of the Supreme Court in Medtronic, Inc. v. Lohr, 116 S.Ct. 2240, 2256 (1996) found to be entitled to substantial weight:

> State or local regulations are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by [the act's preemption clause] because they are not 'requirements applicable to a device' within the meaning of [the preemption clause]. The following are examples of State or local requirements that are not regarded as preempted by [the preemption clause]:
> (1) [The preemption clause] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g. requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or unfair trade

> practices in which the requirements are not limited to devices.
> (2) [The preemption clause] does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

21 C.F.R. § 808.1(d).

In Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir. 1993), the Fifth Circuit held that the MDA preempted state law claims for defective design, inadequate warnings, and negligent failure to warn with respect to collagen implants which had undergone PMA review. The court found that the FDA scrutinizes the labeling, design, and manufacturing of a product during the PMA process, and that the plain language of the MDA preempts state law tort suits which would impose requirements different from those imposed by the FDA.

In 1996, the Supreme Court decided Medtronic, Inc. v. Lohr, 116 S.Ct. 2240 (1996), and shed some light on the preemptive effect of the MDA. The Court held that state law claims against Medtronic for an allegedly defective pacemaker were not preempted by the MDA. Importantly, the pacemaker at issue in that case, unlike the one currently before this Court, had not undergone full PMA review. The pacemaker in Lohr was deemed substantially equivalent to a pacemaker already on the market when the MDA was enacted, so it was approved by the FDA under the far less rigorous § 510k exception.

The Lohr decision settled some issues. At least five Justices agreed that state law tort actions are "requirements" which the MDA can potentially preempt. 116 S.Ct. at 2259, 2262. The Court was unanimous that because the § 510k procedure says nothing about a product's safety, the FDA's § 510k approval of a product does not preempt a state law claim

that the product is defectively designed. Id. at 2254, 2263-64. A majority of the Court also held that FDA Good Manufacturing Practices and labeling requirements are not sufficiently specific and do not relate only to medical devices, so they do not preempt state law claims for manufacturing defects and failure to warn. Id. at 2258. Finally, the Court was unanimous that claims for products manufactured in *violation* of FDA requirements are not preempted. Id. at 2255, 2264.

The Lohr case does not address the situation before this Court in which the allegedly defective product received the more rigorous PMA scrutiny from the FDA. This Court finds that the Lohr case is distinguishable, because as a majority of the Court stated: "[t]he 510(k) process is focused on *equivalence*, not safety." 116 S.Ct. at 2254. The PMA process is focused on safety -- PMA means that the FDA has received "resonable assurance" that a device is both safe and effective. 21 U.S.C. § 360c(a)(1)(C). Although a count of the positions of Supreme Court Justices from the concurrence and dissent is not binding, this Court also notes that at least five Justices would likely support the preemption of state law concerning a device which had gone through the PMA process.

Nearly all courts which have considered the issue in the wake of Lohr have agreed with this position. See Martin v. Telectronics Pacing Systems, Inc., 105 F.3d 1090 (6th Cir. 1997) (state law products liability and misrepresentation claims concerning an allegedly defective pacemaker were preempted by MDA where pacemaker had received investigational device exemption {IDE), requiring a process similar but not identical to PMA); Chambers v. Osteonics Corp., 109 F.3d 1243 (7th Cir. 1997) (strict liability and breach of implied warranty claims concerning prosthetic hip which had received IDE were preempted, but claim that the manufacturer did not follow approved FDA procedures was not preempted); Berish v.

Richards Medical Co., 937 F. Supp. 181 (N.D.N.Y. 1996) (same); Arthur Fry v. Allergan Medical Optics, et al., 695 A.2d 511 (R.I. 1997} (claims for allegedly defective intraocular lens implant which had undergone PMA review were preempted); Green v. Dolsky, 685 A.2d 110 (Pa. 1996) (same holding for collagen implants); but see Rodriguez-Suris v. Montesinos, 935 F. Supp. 71, 75 n.3 (D. Puerto Rico 1996).

The Court therefore follows pre-Lohr Fifth Circuit precedent, the implication from Lohr, and the vast majority of cases decided since Lohr, and holds that § 360k of the MDA preempts some state claims brought against the manufacturers of products which have obtained PMA from the FDA. The remaining question is which claims are preempted.

II. PLAINTIFF'S CAUSE OF ACTION

At a hearing on August 5, 1997, Plaintiff represented to the Court that she had three causes of action: (1) a claim that the pacemaker lead was unreasonably dangerous as designed; (2) a claim that the pacemaker lead was unreasonably dangerous as manufactured; and (3) a claim that Medtronic breached an implied warranty that the lead was safe and fit for the purposes for which it was intended. The Court notes that Plaintiff's original complaint makes several other claims, including a claim for negligent failure to warn.

The Court finds that any claim challenging the design of the Model 4004 ventricular lead is preempted by § 360k and the pre-market approval of the lead by the FDA. The rigorous PMA process certainly constitutes a specific federal requirement relating to the design of the lead, and allowing a state common law suit challenging that design to go forward could impose additional and even inconsistent requirements.

The Court also finds that any claim in which the Plaintiff challenges the manufacturing processes which were approved by the FDA is preempted. Although the Court notes that the Lohr Court held that general Good Manufacturing Practices were not sufficiently specific to preempt manufacturing defect claims, here the FDA approved specific manufacturing plans as part of the PMA process. Similarly, the Court finds that any claim in which the Plaintiff challenges the adequacy of the warnings which were approved by the FDA is preempted. Although general labeling requirements are not enough to create federal preemption, here the FDA specifically approved the packaging, labels, and supplemental materials which were to accompany the lead. In fact, any change in the manufacturing or labeling that could effect the Model 4004 lead's safety and effectiveness would have required prior FDA approval. 21 U.S.C. § 36Oe(e)(1)(B),(E); 21 C.F.R. § 814.39(a).

The claims described above are preempted whether they are couched in terms of products liability, breach of warranty, negligence, gross negligence, or state law deceptive trade practices. This does not mean that all potential claims are preempted. For example, Plaintiff could claim that the manufacturing processes, specifications, or materials actually used by Medtronic were not the same as those that were approved by the FDA. The Court therefore grants the parties 120 days to conduct discovery in order to determine whether Plaintiff wishes to press any non-preempted claims.

CONCLUSION

For these reasons the Court grants in part and denies in part Defendant's motion for summary judgment. The parties are granted 120 days to conduct further discovery in order to determine whether any viable claims remain.

ORDERED this 8 day of August, 1997.

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H. W. HEAD, JR.
UNITED STATES DISTRICT JUDGE

THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

LIRBA SALAZAR

V.

MEDTRONIC, INC.

CA. NO. C-96-425

ENTERED August 27, 1999

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND DENYING PLAINTIFF'S MOTION FOR RECONSIDERATION

This is a products liability suit. Jurisdiction is proper in the Court because there is complete diversity of the parties, 28 U.S.C. 1332.

Plaintiff claims she was injured when a Model 4004M ventricular lead in a pacemaker manufactured by defendant failed after implantation. Defendant moved for summary judgment on the grounds that plaintiff's claims are preempted by § 360k of the Mdeical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act, 21 U.S.C. § 360k. The Court granted in part and denied in part defendant's motion because the device in question received full pre-market approval (PMA) from the FDA and, therefore, § 360k preempted some, but not

all, of plaintiff's potential claims. Specifically, the Court noted that "[p]laintiff could claim that the manufacturing processes, specifications, or materials actually used by [defendant] were not the same as those approved by the FDA," and granted additional time to conduct discovery and determine whether non-preempted claims existed. Plaintiff has not offered evidence that the processes, specifications, or materials defendant used in manufacturing the Model 4004M ventricular leads differed from the approved processes, specification, or materials. Accordingly, the Court grants defendant's renewed motion for summary judgment on this remaining issue.

In her Memorandum Brief, plaintiff suggests the Court reconsider and find her claims are not preempted by the MDA, set aside its order granting partial summary judgment, and schedule this case for trial on all claims. Plaintiff argues the Court should withdraw its previous order granting defendant's motion for summary judgment because of the United States Court of Appeals for the Eleventh Circuit's recent decision in *Goodlin v. Medtronic Inc.*, 167 F.3d 367 (11th Cir. 1999). The Eleventh Circuit found 21 U.S.C. § 360(k) does not preempt state law claims based on the failure of Medtronic Model 4004M ventricular leads. *Goodlin v. Medtronic Inc.*, 167 F.3d 1367, 1377 (11th Cir. 1999). In *Goodlin*, the Eleventh Circuit's decision was based on its finding that the PMA process did not impose specific federal requirements. Id. at 1373-1377. The Fifth Circuit has held to the contrary. *See Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421-23 (5th Cir. 1993), *cert. denied*, 114 S.Ct. 86 (1993). The Seventh Circuit has also concluded that the PMA process imposes specific federal requirements. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997), *cert denied*, 118 S.Ct. 1300 (1998). The Court follows the Fifth Circuit's conclusion in *Stamps* and the Seventh Circuit's conclusion in *Mitchell*. Accordingly, the Court denies plaintiff's motion for reconsideration.

ORDERED this 25 day of August, 1999.

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H. W. HEAD, JR.
UNITED STATES DISTRICT JUDGE